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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| EXAMINER | |
|---|---|
| CROUCH, DEBORAH | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1632 | |

| NOTIFICATION DATE | DELIVERY MODE |
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| 07/09/2007 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/523,643 | EULENBERG ET AL. | |
| | Examiner | Art Unit | |
| | Deborah Crouch, Ph.D. | 1632 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *04 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-35* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 9, 11-17, 29 and 33, drawn to a pharmaceutical composition comprising a minibrain homologous protein and or a functional fragment thereof; use of a mini brain homologous protein; use of a minibrain homologous protein to prepare a medicament; and a kit, classified in class 514, subclass 12.

II. Claims 1-7, 11-17, 28, 30 and 33, drawn to a pharmaceutical composition comprising a nucleic acid molecule encoding a minibrain homologous protein and/or a functional fragment thereof; use of a nucleic acid encoding a mini brain homologous protein; use of a nucleic acid encoding a minibrain homologous protein to prepare a medicament; and a kit, classified in class 514, subclass 44.

III. Claims 1 and 11-17, drawn to a pharmaceutical composition comprising a modulator of a nucleic acid molecule encoding a minibrain homologous protein and or a functional fragment thereof; use of modulator of a nucleic acid molecule encoding a mini brain homologous protein; use of a modulator of a nucleic acid encoding a minibrain homologous protein to prepare a medicament, classified in class 514, class 1+.

IV. Claim 1 and 11-17, drawn to a pharmaceutical composition comprising a modulator of a minibrain homologous protein and or a functional fragment thereof; use of a modulator of a mini brain homologous protein; use of a modulator of a minibrain homologous protein to prepare a medicament, classified in class 514, subclass 1+.

V. Claim 19, drawn to a transgenic animal exhibiting increased expression of a minibrain homologous polypeptide, classified in class 800, subclass 13.

VI. Claim 19, drawn to a transgenic animal exhibiting reduced expression of a minibrain homologous polypeptide, classified in class 800, subclass 13.

VII. Claims 20, 21 and 33, drawn to a recombinant host cell exhibiting modified expression of a minibrain homologous polypeptide and a kit, classified in class 435, subclass 325+

VIII. Claim 22, drawn to a method of identifying a polypeptide involved in the regulation of energy homeostasis or/and metabolism of triglyceride comprising binding a collection of polypeptides with a minibrain homologous protein or function fragment thereof, classified in class 435, subclass 7.2

IX. Claim 23, drawn to a method of screening for an agent which modulates/effects the interaction of a minibrain homologous polypeptide with a binding target, comprising the steps of incubating a mixture comprising a minibrain homologous polypeptide or a functional fragment thereof; a binding target/agent of said polypeptide or functional fragment thereof; and a candidate agent under conditions whereby said polypeptide or functional fragment thereof specifically binds to said binding target/agent at a reference affinity, classified in class 435, subclass 7.2

X. Claim 24, drawn to a method of screening for an agent which modulates/effects the interaction of a minibrain homologous polypeptide with a binding target, comprising the steps of incubating a mixture comprising a minibrain homologous polypeptide or a functional fragment thereof; a binding target/agent of said polypeptide or functional fragment thereof; and a candidate agent under conditions whereby said polypeptide or functional fragment thereof specifically binds to said binding target/agent at a reference affinity, classified in class 435, subclass 7.1.

XI. Claims 25-27, drawn to a method of producing a composition comprising mixing a polypeptide that binds to a minibrain homologous protein with a pharmaceutically acceptable carrier, classified in class 514, subclass 1+.

XII. Claim 31, drawn to use of a host cell exhibiting modified expression of a minibrain homologous polypeptide for the preparation of a medicament, classified in class 424, subclass 93.21.

XIII. Claim 33, drawn to a kit comprising an antibody, classified in class 530, subclass 380.1.

XIV. Claim 33, drawn to a kit comprising an antisense oligonucleotide, classified in class 536, subclass 24.5.

XV. Claims 34 and 35, drawn to a method of producing a composition comprising mixing an agent which modulates/effects the interaction of a minibrain homologous polypeptide with a binding target with a pharmaceutically acceptable carrier, classified in class 514, subclass 1+.

Further, a restriction election requirement is made for the human homologs listed in Table 1 of the specification. Each human homolog encodes a nucleic acid sequence of different nucleotide sequence that renders each member of the table patentably distinct. In such situations where patentably distinct nucleic acid or amino acid sequences are claimed or subject matter of a claim, restriction is proper. Note this is a restriction requirement, not an election of species.

Claims 18 and 32 link(s) inventions V and VI. The restriction requirement between the linked inventions is **subject to** the nonallowance of the linking claim(s), claims 18 and 32. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully

examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Inventions I-IV are directed to related pharmaceutical compositions, methods of using the pharmaceutical compositions and kits. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed each have materially different mode of operation. Invention I operates by supplying exogenous minibrain homologous protein. Invention II operates by supplying a nucleic acid sequence encoding a minibrain homologous protein. Invention III operates by supplying a modulator of a nucleic acid encoding a minibrain homologous protein. Invention IV operates by supplying a modulator of a minibrain homologous protein. Furthermore, the inventions as claimed do not obvious variants.

Inventions I-IV and inventions V-XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different

designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions V-XV have materially different modes of operation that do not require any of inventions I-V.

Inventions V and VI, and inventions VII-XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions the transgenic animals of invention V and VI are of different operation, that is a model for overexpression and underexpression of minibrain homologous protein, from any of inventions VII-XV.

Inventions V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are of different operation. The transgenic animal of invention V overexpresses a minibrain homologous protein. The transgenic animal of invention VI under expresses a minibrain homologous protein.

Inventions VII, and inventions VIII-XI and XIII-XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different effects. Invention VII is to a recombinant host cell comprising a nucleic acid encoding a homologous minibrain protein. The cell can express the protein in vitro. None of methods I-VI and VIII-XV require such operation.

Inventions VII and XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or

(2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the host cell of invention VII can be used to produce recombinant minibrain homologous protein in vitro.

Inventions VIII-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are of different modes of operation. Inventions VIII-X are to methods of identifying agents or screening for agents that affect function of a minibrain homologous protein. However, each method requires materially different and nonobvious method steps.

Inventions VIII-X, ad inventions XII-XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are of different modes of operation. Inventions VIII-X are to methods of identifying agents or screening for agents that affect function of a minibrain homologous protein. None of inventions X-XIV require these methods.

Inventions VIII-X and inventions XI and XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different effects. Each of inventions VIII-X are to methods of identifying or methods of screening agents for effects on minibrain homologous protein. Invention XI to a method of producing a composition from an agent identified. The methods have materially different and separate method steps that are not overlapping.

Each of inventions XI and XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant

case, the different inventions are of separate design. The method of producing compositions of inventions XI and XV are materially different and separate as the agents used in the composition have materially different and separate modes of action.

Inventions XII and inventions XIII-XV are unrelated. Inventions are unrelated if it can t shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are of different modes of operation. The method of invention XII does not require the antibody kit of invention XIII, the antisense kit of invention XV or the method of producing a composition of invention XV.

Inventions XIII and XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are of separate modes of operation. The antibody kit contains a protein antibody that to a homologous minibrain protein that binds to the protein and inhibits its activity. The antisense kit contains a nucleic acid sequence that binds to a nucleic acid encoding a homologous minibrain protein and inhibits production of the protein.

Inventions XIII and XIV, and invention XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). The antibody kit and the antisense kit of inventions XIII and XIV each have different modes of action from the method of producing a composition of invention XV.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further,

note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is 571-272-0727. The examiner can normally be reached on M-Fri, 6:00 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Deborah Crouch

Deborah Crouch, Ph.D.
Primary Examiner
Art Unit 1632

June 25, 2007